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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,265	02/02/2001	Mark A. Christopherson	P-9126.00	9662

27581 7590 11/18/2003

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EXAMINER

MCCROSKY, DAVID J

ART UNIT PAPER NUMBER

3736

DATE MAILED: 11/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/776,265

Applicant(s)

CHRISTOPHERSON ET AL.

Examiner

David J. McCrosky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003 and 03 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on September 2, 2003, PROSECUTION IS
HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the
following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply
under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied
by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130,
1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Objections

Claim 8 is objected to because of the following informalities: "an implantable
medical device" in line 5 should be --the implantable medical device-- to refer to its
antecedent located in the preamble; "a" in line 10 before "remote center" should be
--the-- to refer to its antecedent located in the preamble. Appropriate correction is
required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of
making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the
art to which it pertains, or with which it is most nearly connected, to make and use the same and shall
set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for accessing IMD data, downloading barometric pressure data and transferring data to a remote center, does not reasonably provide enablement for combining the data to produce corrected cardiac pressure data based on the barometric pressure data and transferring the corrected data. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification describes an IRM that obtains data from an IMD or an external pressure reference and transfers data to a remote location. See p. 13, ll. 9-15 and p. 15, 26-31. The specification does not enable a person skilled in the art to combine data to produce corrected data nor does the specification enable one to produce the corrected data and transfer it to a remote center.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-10, 12, 13, 16, 17, 19-21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halperin et al (cited by Applicant) in view of Krichen et al. Halperin et al teach a telemetry system with a barometric pressure sensor attached to the external device i.e. the IRM. The IMD and IRM are in wireless communication as illustrated by Figure 2. The external device receives the data from the barometric pressure sensor, transmits to the programmer, which compares the data. See Figure 5. The reference does not teach an IRM in communication with a remote center. However, Krichen et al teach that it is well known in the art to have a programmer in communication with a remote site. Krichen et al teach a system of transferring information from an IMD having a pressure sensor through an IRM to a remote location. See abstract; col. 6, ll. 17-19; and claims 1, 5 and 13. As illustrated in Figure 7, a computer is interfaced between the IRM and the remote center. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Halperin et al with the communication system of Krichen et al in order to provide information at a remote location.

Regarding claims 10, 21 and 22, the communication link is described in Krichen et al as any type of connection, including Internet, LAN or telephone line. See col. 11, l. 65 to col. 12, l. 2.

Regarding claims 13 and 16, in Halperin et al, an IRM with a housing and antenna (communications pad 19) is illustrated in Figure 1. Various connections are taught in Krichen et al. See col. 11, ll. 56-59.

Regarding claim 19, Halperin et al teach simultaneous recording. See col. 5, l. 50 to col. 6, l. 6.

Regarding claim 20, Krichen et al teach that a programmer (IMR) is essentially a personal computer. See col. 12, ll. 3-11.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Halperin et al in view of Krichen et al as applied to claim 8 above, and further in view of Schroepfel et al. Halperin et al and Krichen et al disclose a health information management system having an IRM with an antenna as recited for claim 8. The combination does not teach data collection after an event. However, Schroepfel et al teach an implantable medical device responsive to heart rate for evaluating heart rate variability in order to forecast a cardiac event. See abstract. Increased level of data collection occurs if the patient experiences tachycardia. See col. 9, ll. 7-28. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the IMD of Halperin et al and Krichen et al with a means for increased data collection, as taught by Schroepfel et al, for evaluating heart rate variability in order to forecast a cardiac event.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Halperin et al in view of Krichen et al as applied to claims 8 and 13 above, and further in view of McKinnon et al. Halperin et al and Krichen et al disclose a health information

management system as recited for claims 8 and 13. The combination does not teach a housing having a front and back panel and a top structure with a slot. However, McKinnon et al teach a portable data collection device that is inserted into a slot on the top surface of a docking station for downloading data. See col. 3; col. 4, ll. 7-11; and Figure 1. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Halperin et al and Krichen et al with a docking station, as taught by McKinnon et al, to download data from a portable device.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Halperin et al in view of Krichen et al as applied to claims 8 and 13 above, and further in view of Winkler (cited by Applicant). Halperin et al and Krichen et al disclose a health information management system having an IRM with an antenna as recited for claims 8 and 13. The combination does not teach a cradle to support the antenna. However, Winkler discloses a cradle to store the programming head (Applicant's antenna). See col. 6, ll. 46-55. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the IRM of Halperin et al and Krichen et al with a cradle, as taught by Winkler, for storage of the antenna.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Halperin et al in view of Krichen et al as applied to claims 8 and 13 above, and further in view of Kumar et al. Halperin et al and Krichen et al disclose a health information management system as recited for claims 8 and 13. The combination does not teach indicators for data download. However, Kumar et al teach a remote monitoring system. A user interface to the signal transfer unit is provided. See Figure 3. An indicator for data

download from the sensor, power and data transfer is provided. See col. 11, ll. 3-16 and col. 12, ll. 20-24. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Halperin et al and Krichen et al with the data transmission indicators taught by Kumar et al in order to insure proper transmission.

Response to Arguments

Applicant's arguments in the appeal brief with respect to claims 8-22 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments in the appeal brief restate what has been presented during prosecution. Examiner has addressed the arguments in previous advisory actions.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. McCrosky whose telephone number is 703-305-1331. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

DJM


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